

Federal Register Notice

Date: July 12, 2007

Title: Nanoscale Materials Stewardship Program and Inventory
Status of Nanoscale Substances under the Toxic Substances
Control Act; Notice of Availability

PREPUBLICATION COPY NOTICE:

The Assistant Administrator for Prevention, Pesticides, and Toxic Substances has signed the following *Federal Register* document on July 9, 2007.

This is a prepublication version of the *Federal Register* document that EPA is submitting for publication in the *Federal Register*. While the Agency has taken steps to ensure the accuracy of this prepublication version of the document, it is not the official version of the document for purposes of public comment. Please refer to the official version of the document that will appear in a forthcoming *Federal Register* publication, which is currently expected to occur on Thursday, July 12, 2007.

Once the official version of the document publishes in the *Federal Register*, the advance publication version of the document posted on the internet will be replaced with a link to the document that appears in the *Federal Register* publication, or a link to the copy of the document in the docket at <http://www.regulations.gov>.

You can use EPA's electronic docket and comment system at www.regulations.gov to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. For further information about the docket and commenting, please consult the ADDRESSES section in the front of the Federal Register document.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2004–0122; FRL–8139–2]

Nanoscale Materials Stewardship Program and Inventory Status of Nanoscale Substances under the Toxic Substances Control Act; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On October 18, 2006, EPA invited stakeholders to participate in the design, development, and implementation of a Nanoscale Materials Stewardship Program (NMSP) under the Toxic Substances Control Act (TSCA). NMSP is a voluntary program intended to complement and support EPA's new and existing chemical programs under TSCA and will help provide a firmer scientific foundation for regulatory decisions by encouraging the development of key scientific information and appropriate risk management practices for nanoscale chemical substances ("nanoscale materials"). As part of this process, EPA is announcing the availability of two draft documents for public review and comment: "TSCA Inventory Status of Nanoscale Substances—General Approach" and "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA." The first document describes EPA's current thinking regarding whether a nanoscale material is a "new" or "existing" chemical substance under TSCA. The second document describes the Agency's general approach, issues, and considerations for NMSP and is intended to serve as a starting point for continuing work with stakeholders on the detailed design of NMSP.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2004–0122, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2004–0122. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of

operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2004–0122. EPA’s policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/

DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: James Alwood, Chemical Control Division, Office of Pollution Prevention and Toxics (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8974; e-mail address: *alwood.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use nanoscale materials that are chemical substances subject to the jurisdiction of TSCA. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (NAICS code 325), e.g., persons manufacturing, importing, processing, or using chemicals for commercial purposes.
- Petroleum and coal product industries (NAICS code 324), e.g., persons manufacturing, importing, processing, or using chemicals for commercial purposes.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this action. Other types of entities not listed in this unit could also be interested. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must

be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

C. Where Can I Access More Information About Nanotechnology?

For more information about nanotechnology under TSCA, go to <http://www.epa.gov/oppt/nano>.

II. Background

A. What is the Applicable Legal Authority?

NMSP is a voluntary program intended to complement and support EPA's new and existing chemical programs under TSCA. TSCA provides EPA authority to assure that new and existing chemical substances are manufactured, processed, used, and disposed of in a manner that protects against unreasonable risks to human health and the environment. TSCA applies to "chemical substances." Nanoscale materials which meet the TSCA definition of "chemical substances" are subject to TSCA.

B. What Action is the Agency Taking?

EPA is announcing the availability of two documents for public review and comment. One document, entitled "TSCA Inventory Status

of Nanoscale Substances—General Approach,” (“TSCA Inventory paper”) describes EPA’s general approach to determining whether a nanoscale material is a “new” or “existing” chemical substance under TSCA. The other document, entitled “Concept Paper for the Nanoscale Materials Stewardship Program under the TSCA,” is a concept paper describing a general approach, issues, and considerations for NMSP.

In a separate notice in this **Federal Register**, EPA is also issuing the draft Information Collection Request (ICR) covering the information collection related activities related to NMSP and the estimated paperwork burdens associated with those activities. Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid control number issued by the Office of Management and Budget (OMB). PRA also applies to voluntarily submitted information. Before submitting an ICR to OMB for review and approval, the agency must first solicit comment on the draft ICR. The draft ICR covering the potential information collection activities related to NMSP is also being made available for public review and comment.

C. Why is EPA taking this Action?

There is a growing class of materials commonly referred to as engineered nanoscale materials. Materials having structures with dimensions in the nanoscale (approximately 1–100 nanometers (nm)), also known as nanoscale materials or nanoscale substances, may have organizations and properties different than the same chemical substances with structures at a larger scale.

Nanoscale materials that meet the TSCA section 3(2)(A) definition of “chemical substance” are subject to TSCA. TSCA provides EPA with a strong framework for ensuring that new and existing chemical substances are manufactured and used in a manner that protects human health and the environment. TSCA distinguishes between “new” and “existing” chemical substances. Existing chemicals are those substances contained on the TSCA Inventory. New chemicals are those substances not contained on the TSCA Inventory. Under section 5 of TSCA, EPA requires manufacturers of nanoscale materials that are new chemicals, to notify the Agency 90 days prior to manufacture. The draft paper, “TSCA Inventory Status of Nanoscale,” is intended to explain the Agency’s current thinking on this question of “new” versus “existing” within the context of nanoscale materials.

On October 18, 2006, EPA launched a collaborative process and invited stakeholders to participate in the design, development, and implementation of a NMSP under TSCA. EPA is developing NMSP to complement and support its new and existing chemical efforts on nanoscale materials. As outlined in the “Concept Paper for the NMSP under TSCA,” the program is envisioned primarily for manufacturers of nanoscale materials that would be considered existing chemical

substances under TSCA (though persons at a variety of stages of product development are also encouraged to participate). Manufacturers of existing chemical substances are not required to submit pre-manufacture notices to EPA under section 5 of TSCA. NMSP will also help provide a firmer scientific foundation for regulatory decisions by encouraging the development of key scientific information and appropriate risk management practices for nanoscale chemical substances (“nanoscale materials”).

EPA developed the concept paper to outline its initial thinking about NMSP. The Agency will be working collaboratively with other Federal agencies and stakeholders to further develop and implement NMSP. Although dependent on the outcome of this development process, the Agency envisions that the components of the program could include:

- Assembling existing data and information from manufacturers and processors of existing chemical nanoscale materials.
- Encouraging the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions.
- Identifying and encouraging use of a basic set of risk management practices in developing and commercializing nanoscale materials.

The concept paper outlines proposed ideas for reporting on nanoscale materials in commerce, developing data on representative nanoscale materials, and identifying risk management practices. It describes who may wish to participate, the reporting expectations for participants, what the program could entail and what EPA intends to do with the data generated from the program. It also describes the potential benefits of participation.

EPA will use the data from NMSP to gain an understanding of which nanoscale materials are produced, in what quantities, how they are used, and the data that is available for such materials. EPA scientists will use data collected through this program, where appropriate, to aid in determining how and whether certain nanoscale materials or categories of nanoscale materials may present risks to human health and the environment.

This release of the two draft documents for public review and comment are an important part of the collaborative development process for NMSP. These draft documents are intended to further discussion about NMSP and will serve as the foundation for establishing the details of NMSP.

The Agency also intends to conduct a public meeting to obtain further public comment on these documents and any other issues pertaining to a NMSP and will announce that meeting date in a separate

Federal Register notice. EPA will consider all comments and announce the availability in the **Federal Register** of the final versions of the ICR, TSCA Inventory paper and a document that describes NMSP. Once the details of NMSP have been announced, EPA will implement NMSP.

III. Request for Comments

While EPA is seeking comment on all aspects of NMSP and the TSCA Inventory paper, the Agency is especially interested in comments on the following items:

1. Whether the data elements that have been identified in NMSP are appropriate for nanoscale materials.
2. Timing and phasing of submissions under the NMSP basic and in-depth programs and whether approaches for tiering data submissions are appropriate.
3. Who would participate in NMSP and how to encourage participation, especially from small and medium sized enterprises.
4. What criteria to use for NMSP program evaluation and views on the timing and nature of any reports the Agency may issue.
5. How to engage industry and other stakeholders in the NMSP in-depth program and approaches for generating test data.
6. The processes and roles for EPA, participants, and other stakeholders during development and evaluation of data for the in-depth program.
7. Possible approaches for identification and use of alternative sources of data, in order to minimize the burden of information collection associated with NMSP.
8. Uses for the data submitted to EPA under the NMSP program.
9. Issues relevant to scope, definitions, and descriptions.
10. The suitability of the approach for determining the TSCA Inventory status of nanoscale materials discussed in the TSCA Inventory paper referenced in Unit II.C.
11. Whether, in combination, the TSCA Inventory paper and the NMSP concept paper are sufficiently clear in how EPA plans at this time to address nanoscale materials that are new or existing chemicals under TSCA and the NMSP and, if needed, an indication of areas where further clarification may be warranted.

IV. Summary of Next Steps

As indicated previously, EPA intends to use a collaborative process that involves stakeholders in the design, development, and implementation of NMSP. In addition to providing comments on the

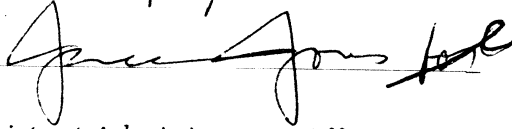
draft documents released by this document, EPA invites you to participate in the process. If you would like EPA to notify you as the stewardship program moves forward, please sign-up at <http://www.epa.gov/oppt/nano/nano-contact.htm>.

EPA will announce the date and logistics of a public meeting on NMSP in a separate **Federal Register** notice and the TSCA nanotechnology website <http://www.epa.gov/oppt/nano>.

Following consideration of all comments received on this notice, EPA will announce availability in the **Federal Register** of the final versions of the ICR, TSCA Inventory paper, and a document that describes NMSP. Once the details of the NMSP have been developed and announced, EPA will implement NMSP.

List of Subjects

Environmental protection, Chemicals, Hazardous substances,
Nanoscale materials.

Dated: 7/9/07

James Jones, Acting

*Assistant Administrator, Office of Prevention, Pesticides and Toxic
Substances.*

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